# Ethylene Oxide Hazards and Reduction Example

Healthcare facilities and commercial sterilization facilities often use ethylene oxide (EtO) to sterilize moisture and heat-sensitive medical instruments. This fact sheet provides background information on the hazards of EtO and describes the significant EtO reduction achieved at a healthcare facility in Minnesota.

## EtO Hazards

EtO is listed as a hazardous air pollutant in the 1990 Clean Air Act Amendments. In December 2016, the U.S. Environmental Protection Agency updated its EtO inhalation cancer risk estimate. The prior estimate was based on experimental animal results, while the 2016 estimate relies more on human study data. Formerly categorized as a probable carcinogen, the 2016 update concluded EtO is carcinogenic to humans, in agreement with the International Agency for Research on Cancer (2012).

Human studies show that sufficient exposure to EtO may result in lymphoid cancer and breast cancer in females. Depending on exposure assumptions, the updated EtO inhalation cancer risk estimate is about 30-60 times higher than prior values. This means EPA now believes EtO is considerably more potent than previously thought for inducing human cancer. Evidence considered in the 2016 update indicates children under 16 years of age have greater susceptibility to EtO's inhalation cancer risk[1].The updated EtO cancer potency information supports the need to reduce EtO air emissions.

In addition to the cancer risk, EtO poses several other health hazards:

- Inhaling EtO at elevated concentrations can cause nausea, vomiting, and neurological disorders.
- In solution, EtO can severely irritate and burn the skin, eyes and lungs.
- EtO may damage the central nervous system, liver, and kidneys, or cause cataracts.
- EtO is also extremely reactive and flammable, increasing the risk of chemical accidents that could injure hospital employees and patients. Even static electricity can cause EtO to ignite; therefore, employees using it should be well-trained and aware of its potential dangers. While EtO is reactive, it is sufficiently persistent in the atmosphere that EtO emissions causes community exposure; its half-life in air ranges from 69 to 149 days[2].

### A Success Story – Minnesota VA

Since 2013, the Minnesota VA Health Care System (MN VA) has reduced the amount of EtO used by its on-site sterilizer by 50 percent. In 2013, the MN VA sterilized 200 loads of instruments using EtO and they reduced that number to 101 in 2017.

The Department of Veterans Affairs National Program Office for Sterile Processing issued guidance in 2011, recommending the reduction of the volume of EtO used within facilities. Also, VA facilities were requested to keep a list of all instruments that required EtO sterilization and to systematically replace them with models that could be sterilized using alternative methods of sterilization.

The MN VA currently uses Hydrogen Peroxide Sterilization to sterilize a large portion of the facility's instruments. To make the transition, the MN VA consulted Hydrogen Peroxide equipment manufacturers' websites to review instrument/equipment compatibility information. The websites list instruments by make and model that could be sterilized by hydrogen peroxide technology.

Currently, only endoscopes continue to require EtO sterilization at the MN VA, due to the length of the equipment's inner lumen. The specific endoscopes are listed in the Table. **The facility has a goal to be EtO free by December, 2018. It intends to meet the goal by:**

- **purchasing instruments that can be sterilized by other methods; and**
- **if clinically appropriate, performing High Level Disinfection, instead of sterilization.**

1 https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=1025
2 https://www.epa.gov/sites/production/files/2016-09/documents/ethylene-oxide.pdf

# List of Endoscopes Currently Requiring Ethylene Oxide Sterilization at the MN VA

| Item | Make | Model |
|---|---|---|
| Bronchofiberscope EBUS | Olympus | BF-UC180 |
| Choledochofiberscope | Olympus | CHF-CB30s |
| Colonoscope | Olympus | Q180AL |
| Esophagoscope | Olympus | GIF-Q180 |
| Esophagoscope | Olympus | GIF-XP160 |
| Ultrasonic Probe | Olympus | UM-S20-20R |
| Ultrasonic Probe | Olympus | UM-S20-17S |
| Generator Magnet | Medtronic | 9466 |
| Gastrointestinal Scope | Olympus | TJF-Q180V |
| Gastrointestinal Scope | Olympus | GIF-1TH190 |
| Gastrointestinal Scope | Olympus | PCF-H190DL |
| Gastrointestinal Scope | Olympus | SIF-Q180 |

**Sterilization Alternatives -** EtO use and emissions can be reduced through alternative sterilization approaches, including:

**Heat:**
*Steam sterilizers/autoclave* are the most common heat treatments. Steam sterilizes medical equipment quickly (within 15 to 60 minutes per batch), providing quick turnaround on their medical devices, while EtO can take in excess of 12 hours. Steam can corrode metal equipment and damage heat-sensitive materials.

**Chemical:**
*Nitrogen Dioxide (NO2)* has several advantages compared with EtO. It sterilizes at room temperatures. EtO requires temperatures of up to 55-65 degrees C. NO2 does not penetrate as deeply, significantly cutting down on aeration time. NO2 is not highly flammable, volatile or a carcinogen, and does not have a reference concentration for inhalation exposure. NO2 contributes to ozone formation and is regulated under the National Ambient Air Quality Standards (NAAQS). NO2 is incompatible with cellulose-based materials such as cardboard, which impacts contract sterilizers more than hospital sterilizers. NO2 requires a different type of sterilization chamber than EtO, eliminating the possibility of a simple, cost-effective equipment conversion.

*Ozone (O3)* is similar to EtO, so EtO sterilizers can be converted for O3 use. However, O3 damages many common materials such as metals, rubber and some plastics. O3 is a main contributor to "smog" formation and also is subject to the NAAQS. Breathing O3 causes respiratory issues ranging from coughing and shortness of breath to inducing asthma attacks and permanent lung damage.

*Vapor-Phase Hydrogen Peroxide (VPHP)* sterilizes more quickly than EtO, however it is incompatible with iron, some plastics and cellulose-based materials. VPHP is a human health risk if not handled properly, but has lower exposure risk than EtO. The typical VPHP control device is the catalytic converter that breaks down hydrogen peroxide into water and oxygen.

*Peracetic Acid* offers a faster turnaround than EtO, due to reduced aeration time. Similar to VPHP, the end byproducts are nontoxic (water, oxygen and vinegar), but there is a potential health risk from exposure during operation. Peracetic acid is a less viable alternative than VPHP, as it often requires full immersion of the equipment, which must be used within two hours to remain sterile.

**Radiation:**
*Gamma-Ray Radiation* uses Cobalt-60 to emit particles that penetrate through many materials except for some polyvinyl plastics. Although equipment is irradiated, the gamma rays do not carry enough energy to leave the equipment radioactive. Gamma-ray radiation would be cost prohibitive if out-sourced, because specialists are required to use the radioactive material. Gamma rays provide a quick turn-around and are a popular choice for single-use products (as multiple doses can discolor/damage plastic materials).

*Electron-Beam Radiation* has similar attributes to gamma-ray radiation, but operates on electricity rather than Cobalt-60, which cannot be turned off. E-beam radiation can sterilize on a continuous basis instead of in batches and uses electricity as an energy source, so operators can control radiation exposure with E-beams allowing for higher doses, quicker turnaround, and increased safety compared with gamma-rays. Despite the dose control, E-beam radiation cannot penetrate high-density materials the way gamma-rays can.